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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) <i>GUID-160PA (03-512)</i>	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>April 29, 2008</u> Signature <u><i>Rennae Johnson</i></u> Typed or printed name <u>Rennae Johnson</u>		Application Number <i>10/735,519</i>	Filed <i>12/12/2003</i>
		First Named Inventor <i>Kim</i>	
		Art Unit <i>3762</i>	Examiner <i>Holmes, R.</i>

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)
- ☐ attorney or agent of record.
Registration number _____
- ☒ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 35,207

Stephen C. Jensen
Signature
Stephen C. Jensen
Typed or printed name
952-854-2700
Telephone number
04/29/2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below.

☒ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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SERIAL NO. 10/735,519

PATENT APPLICATION

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Appellant:	KIM et al.	Examiner:	Holmes, Rex R.
Serial No.:	10/735,519	Group Art Unit:	3762
Filed:	December 12, 2003	Docket No.:	GUID.160PA
Title:	CARDIAC RESPONSE CLASSIFICATION USING MULTISITE SENSING AND PACING		

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this Transmittal Letter and the papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on April 29, 2008.

By 
Rennae Johnson

**APPELLANT'S STATEMENT IN SUPPORT OF
PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This statement is presented by Appellant in compliance with the USPTO OG Notice of 12 July 2005 on New Pre-Appeal Brief Conference Pilot Program. Appellant is requesting a pre-appeal brief conference on the belief that the rejections of record are clearly not proper and are without basis. Appellant's request is based upon a clear legal or factual deficiency in the rejections. As such, Appellant believes this request for pre-appeal review is appropriate.

Claims 1-23, 35-48, 50-60, 62, and 63 are pending. These claims are all rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In particular, the Final Office Action of 01/30/2008 contends that the language "using only the single cardiac signal" and variants thereof in the independent claims (1, 15, 35, 39, 52, 57, 59, and 62) is not disclosed in the original application.

Appellant respectfully submits this is a clearly improper rejection based on errors in facts, and is therefore appropriate for review under the Pre-Appeal Brief Conference

Pilot Program. In short, Appellant's original disclosure describes, among other things, a method of classifying a cardiac response utilizing characteristics of a particular cardiac signal to classify a cardiac response into different categories: if a detected peak of the cardiac signal has an amplitude less than a reference amplitude, the cardiac response is classified into one category; if the peak of the cardiac signal is detected in a particular classification window, the cardiac response is classified into another category; and so forth. Without using the term "only", the description explains how the characteristics of the particular cardiac signal are used--without recourse to other cardiac signals--to classify the cardiac response. Appellant respectfully submits that this original disclosure fully supports the rejected claim language.

Legal Standard. *In haec verba* support for claimed subject matter is not required. See *Lockwood v. American Airlines*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). Rather, under the written description requirement, the disclosure "must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention." *Crown Operations International v. Solutia Inc.*, 289 F.3d 1367, 1376 (Fed. Cir. 2002). The requirement is satisfied by the patentee's disclosure of such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. See *Id.* Stated differently, one skilled in the art, reading the original disclosure, "must reasonably discern the limitation at issue in the claims." *Id.* With this as the standard for compliance with the first paragraph of §112, the as-filed application can be seen to clearly support the disputed language.

Independent claim 1. Claim 1 is reproduced here with the disputed language italicized:

1. A method of determining a cardiac response to a pacing pulse, comprising:
 - providing a plurality of electrodes electrically coupled to a heart;
 - delivering the pacing pulse to the heart using a first electrode combination;
 - sensing a single cardiac signal for cardiac response classification
 - following the pacing pulse using a second electrode combination; and

classifying the cardiac response to the pacing pulse as one of a captured response, a non-captured response, and a fusion/pseudofusion beat *using only the single cardiac signal.*

The person skilled in the art, reading the original disclosure, would reasonably discern all of these limitations, including the italicized portion. Such person would discern the “providing a plurality of electrodes ...” at least in connection with Applicants’ FIG. 1 and its description. He or she would discern the remaining “delivering”, “sensing”, and “classifying” actions in a number of places, but we focus here on Applicants’ FIG. 12, reproduced below, and its associated description:

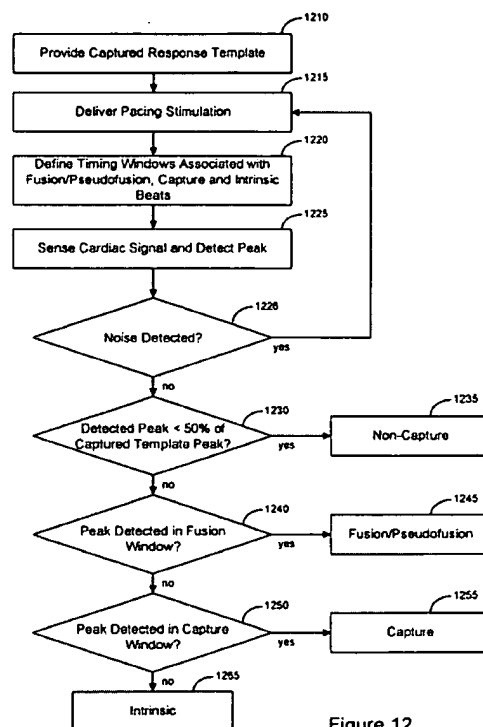


Figure 12

The skilled person reads at page 9 lines 1-3 that FIG. 12 “is a flowchart illustrating a method of classifying a cardiac response using fusion, capture, and intrinsic classification windows in accordance with an embodiment of the invention.” The person then reads the detailed description of the figure, from line 19 of page 42 to line 27 of page 43, in which the entire process from box 1210 through box 1265 is explained. The person discerns from the figure and the description that a pacing pulse is delivered to the heart at box 1215, and that a single cardiac signal is sensed at box 1225, and the peak *of that same signal* is detected. The person then discerns that, if no noise is detected, the cardiac

response to the pacing pulse is classified as one of capture (box 1255), non-capture (box 1235), or fusion/pseudofusion (box 1245) by straightforward operation of the decision boxes 1250, 1230, and 1240 respectively. The person discerns from the decision boxes that these classifications are performed based on properties of the same cardiac signal, namely, the amplitude of the detected peak, and the detected peak's relative position with respect to the described classification windows.

Since the figure is described as “a flowchart illustrating a method of classifying a cardiac response ...”, the person reasonably expects that important aspects of the method are shown or described. Thus, it would be unreasonable for the person to expect an important aspect of the classification method to be omitted. Moreover, the person would consider it important to the method if a signal other than the particular cardiac signal described were used in the classification process. Hence, it would be unreasonable for the person to expect that a signal other than the particular cardiac signal described was used in the classification process. Put another way, the person reasonably discerns from FIG. 12 and its description that the classifying method uses the cardiac signal sensed at box 1225 and no other signal, i.e., that the classifying is performed “using only the single cardiac signal”.

The as-filed application can thus be seen to convey with reasonable clarity to those skilled in the art that the inventors were in possession of the invention now claimed in claim 1. Due to space limitations we have demonstrated this with respect to FIG. 12, but there is an abundance of other disclosure in the as-filed application that leads to the very same conclusion.

Remaining claims. Using the same analysis, we can show that the as-filed application conveys with reasonable clarity to those skilled in the art that the inventors were in possession of the invention now claimed in the other independent claims 15, 35, 39, 52, 57, 59, and 62. The rejections of the independent claims, and of their respective dependent claims 2-14, 16-23, 36-38, 40-48, 50, 51, 53-56, 58, 60, and 63 should therefore be withdrawn and the case should be passed to issuance.

In summary, the rejections of the pending claims are clearly improper and based upon error(s) in facts. This Appellant's Statement, viewed together with the prosecution history, sets forth clear grounds for a finding that the rejections of record are without merit.

Respectfully submitted,

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